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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,727	07/08/2002	Hubert Rein	228.1010	8812
20583	7590	05/11/2007		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/980,727	Applicant(s) REIN ET AL.	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,10,16-18 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,10,16-18 and 20-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's request for continued examination, amendment, response, declaration under 37 C.F.R. § 1.132, and petition for extension of time, all received on 12 February 2007.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 February 2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 10, 16-18, 20 and 22-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentz *et al.*

The Lentz *et al.* document discloses controlled-release starch compositions (See Abstract). The compositions comprise a melt made from a starch/water mixture and an active ingredient. The starch is processed in such a way as to eliminate a granular starch structure, rendering it “destructured”, which can include heating the starch melt above the glass transition temperature (See Page 11, Line 8 to Page 12, Line 30; and Page 17, Line 34 to Page 18, Line 15). This composition is processed under shear at temperatures ranging from about 80°C to about 240°C (See Abstract). This allows for greater compressibility in the formation of tablets (See Page 15, Lines 8-14). Various types of drugs, either water-soluble or -insoluble, may be incorporated into the disclosed controlled-release starch matrices (See Page 15, Line 25 to Page 16, Line 39). Various types of dosage forms, including tablets, capsules, beads, granules, powders, and solids may be formulated from the compositions. Processing techniques that may be used to produce such dosage forms include wet and dry granulation, injection molding, thermoforming, extrusion, co-extrusion, and cast molding (See Page 26, Line 29 to Page 27, Line 21). Release profiles are given which show the release of an active ingredient over a period of 24 hours. The release profile of the active ingredient appears to follow a lapidus function (See Figures 2 & 3).

Although the disclosed release profiles only show drug release up to a period of 24 hours, the amount of drug released in some figures remain under 100%. It is the position of the examiner that the drug release can be extrapolated beyond 24 hours due to the insolubility of the amorphous starch matrix. The instant claims are thus anticipated.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-6, 10, 16-18, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz *et al.*

The Lentz *et al.* document discloses controlled-release starch compositions (See Abstract). The compositions comprise a melt made from a starch/water mixture and an active ingredient. The starch is processed in such a way as to eliminate a granular starch structure, rendering it “destructured”, which can include heating the starch melt above the glass transition temperature (See Page 11, Line 8 to Page 12, Line 30; and Page 17, Line 34 to Page 18, Line 15). This composition is processed under shear at temperatures ranging from about 80°C to about 240°C (See Abstract). This allows for greater compressibility in the formation of tablets (See Page 15, Lines 8-14). Various types of drugs, either water-soluble or -insoluble, may be incorporated into the disclosed controlled-release starch matrices (See Page 15, Line 25 to Page 16, Line 39). Various types of dosage forms, including tablets, capsules, beads, granules, powders, and solids may be formulated from the compositions. Processing techniques that may be used to produce such dosage forms include wet and dry granulation, injection molding, thermoforming, extrusion, co-extrusion, and cast molding (See Page 26, Line 29 to Page 27, Line 21). Release profiles are given which show the release of an active ingredient over a period of 24 hours. The release profile of the active ingredient appears to follow a lapidus function (See Figures 2 & 3).

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Although the prior art does not explicitly disclose the limitations related to feed, screw, and die temperatures, it is the position of the examiner that the manipulation of such parameters would be well within the skill of one of ordinary skill in the art. One of ordinary skill in the art would be motivated to tailor such parameters, since such parameters have a direct impact on the release characteristics of the dosage forms created by the disclosed process. With this knowledge in mind, such processing temperatures may be adjusted as needed to create dosage forms with particular release profiles to suit a particularly desired application (See Example 11 in Lentz *et al.*). Therefore, the instantly claimed invention as a whole is *prima facie* obvious

Response to Arguments

Applicant's arguments filed 12 February 2007 have been fully considered but they are not persuasive.

The applicant's arguments are centered on comparative data from the instantly claimed invention and from the prior art processes. The examiner does greatly appreciate the information provided by the applicant to show the distinction between the instantly claimed invention and the prior art. However, it is not entirely persuasive in that it only focuses on one example given by the prior art. The examiner cannot interpret the prior art as being limited solely to what has been disclosed in the prior art examples.

The declaration under 37 CFR 1.132 filed 12 February 2007 is insufficient to overcome the rejection of Claims 1, 4-6, 10, 16-18, and 20-32 based upon obviousness as set forth in the last Office action because: the showing is not commensurate with the scope of the instant claims.

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The example set forth by the applicant to illustrate the instantly claimed process is provided in only one embodiment, where the temperature profile of the process is kept at 80°C-80°C-80°C, whereas Claim 1 is directed to any exit temperature below 100°C (See Page 20 of the declaration). The demonstration of unexpected results should be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). Because only one example was given by the applicant to show the results that would demonstrate patentability over the prior art, it is difficult to see how this properly illustrates results that are unexpected over what has been broadly taught by Lentz *et al.*

The applicant argues that the temperature range recited in the prior art of about 80°C to about 240°C should be interpreted to mean that the lower end of that range, 80°C, applies only the feed temperature and no other part of the process. However, this assertion is based only upon what has been disclosed in one example. It is the view of the examiner that this not sufficient evidence that the prior art should be limited to such a narrow interpretation. Furthermore, the prior art also teaches an instance where a starch matrix is processed at 70°C, which would therefore read on the recited limitation of processing below 100°C (See Lentz *et al.*, Page 35, Lines 16-18).

Thus, it is the position of the examiner that the applicant's response is based on a narrow interpretation of the prior art. One of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would not find the claimed invention patentable over the disclosure of the prior art. See MPEP § 2111 and 2123. As such, all pending claims are presently rejected.

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Correspondence

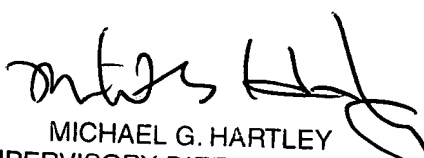
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER